

REMARKS

INTERVIEW SUMMARY

In a telephonic interview with the Examiner on December 16, 2008 (hereinafter, "Interview"), Claims 67, 69, 71, 73, 76, 77, 79, 81-84, 86-92, 94-99, 113, 114, 116-120, 123, 124, 137-150, 152, and 155 were discussed. Attorney Rice requested reconsideration of the objection to the claims for containing nonelected subject matter. Examiner Murray confirmed that Groups VI-X were rejoined in the Mar. 31, 2008 Office Action and will confirm that the currently-pending claims do not contain nonelected subject matter. Attorney Rice stated that the term "heterocyclyl" in the claims would be deleted and, in some instances, be replaced with specific rings from the definition of "heterocyclyl." Examiner Murray stated that he would add a restriction group directed to the scope of Formula Ia, and related compounds, which are not within the scope of Formula I and also would add a restriction group directed to intermediates which are not within the scope of Formula I. The Examiner agreed to reconsider the enablement rejection.

AMENDMENTS

Claims are amended to correct punctuation and typographical errors and to particularly point out and distinctly claim what the Applicants regard as their invention. In particular, Claims 67, 113, and 114 are amended to delete the term "heterocyclyl." In Claims 67, 113, and 114, the group NR^3R^4 , when R^3 and R^4 form a ring together with the nitrogen, is amended so as to represent specific rings. Support for the specific rings is found in the definition of "heterocyclyl" in paragraph [0108] on page 74-75 of the Specification and in the Examples.

Claims 113, 114, and 116 are amended to delete " $-\text{C}(=\text{O})\text{R}^4$ " from R^{13} and " $-\text{OS}(\text{O})_2\text{alkyl}$," "alkyl substituted with alkoxy," and "exo-alkenyl" from R^{11} and R^{12} . In addition, the scope of the ketal formed when two R^{13} 's are taken together has also been amended. Applicants make the amendments with the understanding from the Interview that a new restriction group to be created by the Examiner will be directed to this scope.

Previously-presented and provisionally-withdrawn Claim 127 has been amended to depend from Claim 67, 147, or 148 and includes all of the limitations of the recited claims.

Claim 155 is amended to reduce the multiplicity of claim dependencies in order to reduce fees.

Support for the above amendments are found throughout the Specification. The Applicants believe that no new matter is introduced with the above amendments. The Applicants respectfully request that they be entered into the record.

CLAIM OBJECTIONS

The Applicants thank the Examiner for agreeing during the Interview to reconsider the objection to Claims 79, 84, 89, 113-120, 140, 152, and 155 as containing nonelected subject matter. Applicants believe that the scope of these claims fall within the elected restriction group and do not contain nonelected subject matter. Applicants respectfully request withdrawal of the objection.

ELECTION/RESTRICTIONS

Applicants thank the Examiner for reconsideration of the restriction groups. Agreement was reached during the Interview that the Examiner would add restrictions groups directed to the scope of the invention that does not fall within Formula I.

CLAIM REJECTIONS – 35 USC § 112, 1ST PARAGRAPH

Claims 67, 69, 71, 73, 76, 77, 79, 81-84, 86-92, 94-99, 113, 114, 116-120, 137-150, 152, and 155 are rejected as not enabled for compounds other than where R¹ is “an alkyl; R² is a halogen, alkyl, haloalkyl, methoxy, aryloxy, or piperazinyl group; Z is a -NH- group; and M¹M²M³M⁴ is a -CH₂-bicyclic ring where the bicyclic ring is one of the following 1) 5-octahydrocyclopenta[c]pyrrole group; 2) 3-hexahydro-1H-[1,4]oxazino[3,4-c][1,4]oxazine group; 3) 3-hexahydro-1H-pyrrolo[2,1-c][1,4]oxazine group; 4) 3-octahydro-1H-pyrido-[1,2-a]pyrazin-1-one group; 5) 3-hexahydropyrrolo[1,2-a]pyrazin-1(2H)-one group; 6) 3-hexahydrothiazolo[4,3-c][1,4]oxazine group; 7) 3-octahydro-1H-quinolizine group; and 8) 8-methyl-8-azabicyclo[3.2.1]octane group” (pages 4-5 of the Final Rejection).

The Applicants thank the Examiner for reconsidering the enablement rejection. The Applicants believe that the ring “3-hexahydrofuro-[3,2-b]furan group” was inadvertently dropped from the list of bicyclic rings given in the Final Rejection. This ring was in the original list that the Office considered enabled in the March 31, 2008 Office Action (page 4, group 4)). There are specific examples in the Application which support this bicyclic ring and which are within the elected restriction group. In particular, see Table 1 of the Application, entries 41, 42, 43, 44, 45, 46, 47, and 48, depicted below for convenience.

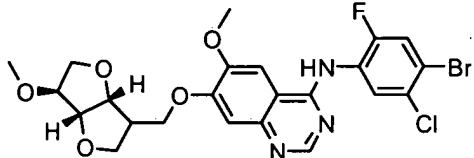
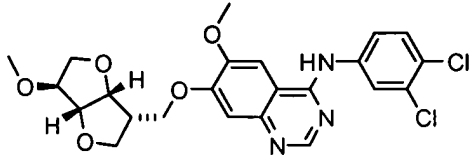
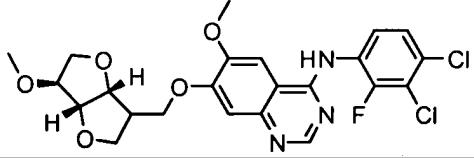
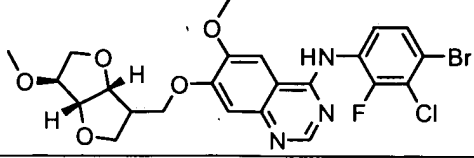
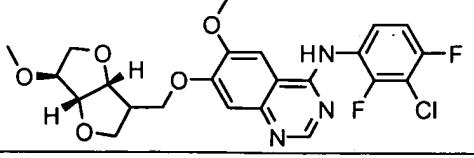
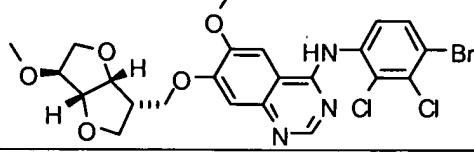
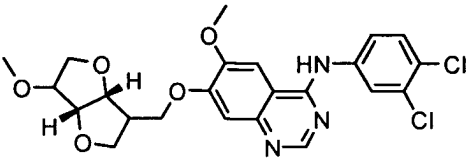
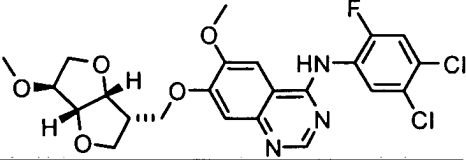
Table 1, entry no.	Structure
41	
42	
43	
44	
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Table 1, entry no.	Structure
47	
48	

The Applicants respectfully request clarification of the Office's position with respect to the enablement of the "3-hexahydrofuro-[3,2-b]furan group."

The Applicants maintain that the Office has not met its initial burden to make a prima facie case of nonenablement. MPEP § 2164.04 states that a specification which describes how to make and use the invention has complied with the enablement requirement "unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." The Applicants have shown how to make the compounds in numerous synthetic examples and have shown how to use the compounds by disclosing assays and ranges of activity of numerous compounds. If the Office believes that there is a reason to doubt that a person of ordinary skill in the art would know how to make and use the invention, it must "... explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." (*In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971)). In this case, the Office has not provided the Applicants with any specific scientific reasoning or evidence why a person of ordinary skill in the art could not make and use Applicants' invention when the disclosure of the Specification is considered in light of what a person of ordinary skill in the art knows. The Applicants respectfully request reconsideration of the rejection.

CLAIM REJECTIONS – 35 USC § 112, 2ND PARAGRAPH

The Office states that the scope of "heterocyclyl" still requires clarification and that the definition is broad and vague (Final Rejection, page 7). Applicants maintain that

the definition is definite and that breadth does not equate with indefiniteness (M.P.E.P. § 2173.04). However, in order to expedite prosecution, the Applicants have amended the claims. The Applicants believe the basis for this rejection has been removed and respectfully request that this rejection be withdrawn.

REQUEST FOR REJOINDER

Applicants respectfully request that Claims 127, 128, and 130-136, which are directed to methods of using the Compounds of the pending Claims, be rejoined.


SUMMARY

In view of the foregoing, the Applicants believe the Application is in condition for allowance and respectfully request entry of the amendments, withdrawal of the objections and rejections, and rejoining of the provisionally-withdrawn claims for the above given reasons.

It is not believed that a fee is due with the submission of this response. Should any fees be required by the USPTO in order to process this submission and the papers attached, the Commissioner is hereby authorized to charge the necessary fees to Deposit Account Number 50-1108.

Respectfully submitted,

December 23, 2008
Date


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